K091113

Pride Mobility Products Corp.

Research & Development
182 Susquehanna Ave
Exeter, PA 18643
570-655-5574
FAX 655-2990
www.pridemobility.com

MAY 1 1 2009

Exhibit 1

510(k) Summary
Pride Mobility Products Corporation
Maxima V – Three and Four Wheel Scooter

Submitter's Name & Address:
Pride Mobility Products Corporation
182 Susquehanna Avenue
Exeter, Pa. 18643
Phone: (570) 655-5574
Facsimile: (570) 655-2990

Contact Person:
Thomas Schappert
Official Correspondent

Date Prepared:
04-03-09

Name of Device and Proprietary Name:
Maxima V, Three and Four Wheel Scooter / Pride Mobility Products Corporation

Common or Usual Name:
Three and Four Wheel Power Scooter

Classification Name:
Physical Medicine / Motorized Three - Wheeled Vehicle

Product Code:
INI

Comparison to Predicate Devices:
The Maxima V, Three and four Wheel Scooters are substantially equivalent to the Pride Mobility Sunrunner SC 400 (K926296), and Sunrunner SC440 (K930953) when comparing, performance, maneuverability, stability, and structure. The performance characteristics and the position of the electronics and drive mechanisms are similar to achieve the same intended use function that enables the user to maintain optimum stability without hindering performance. The major differences between Maxima V, Three and Four Wheel Scooters to the Sunrunner SC400 (K926296) and the Sunrunner SC440 (K930953) are in the weight capacity, Charger, and the Control Mechanisms.

Pride Mobility Products Corp.

Research & Development
182 Susquehanna Ave
Exeter, PA 18643
570-655-5574
FAX 655-2990
www.pridemobility.com

Device Description:
The Maxima V, Three and Four Wheel Scooters are heavy duty battery-operated scooters with programmable Controllers. Features include various size removable seats, a foldable tiller, and an off board charger. The Scooter can be disassembled into four parts: the rear section, the front section, batteries, and seat; this allows for ease of use when travelling or storing the scooter. Additional safety features include electronic regenerative and electromechanical disc brakes, rear anti-tip wheels, and front anti-tip wheels on the three wheel model.
The Maxima V, Three and Four Wheel Scooters are designed with ultimate safety, stability, and performance in mind. The Scooters are designed for, but not limited to Pride Mobility Products Corp. providers / retailers and their consumers.

Intended Use:
The intended use of the Pride Mobility Products Corp. Maxima V, Three and Four Wheel Scooters, is to provide mobility to disabled persons having limited walking capabilities.

Non-Clinical Testing:
Compliance to applicable Testing Standards is as follows:
RESNA WC Vol.1 2008 DRAFT - Requirements and Test Methods for Wheelchairs (Including Scooters)
RESNA WC Vol. 2 2008 DRAFT - Additional Requirements for Wheelchairs (Including Scooters) with Electrical Systems
ANSI/RESNA WC Vol. 2-1998 Section 21 – Requirements and Test Methods for Electromagnetic Compatibility.
IEC 601-1-1 Medical Electrical Equipment, General Requirements for Safety
CAL 117 – Flammability Testing

Discussion of Clinical Testing Performed:
N/A

Conclusions:
The Maxima V, Three and Four Wheel Scooters have the same intended use and similar technological characteristics as the Sunrunner SC400 (K926296) and Sunrunner SC440 (K930953), moreover, the non-clinical testing and the predicate comparisons demonstrate that any differences in their technological characteristics do not raise any new questions of safety or effectiveness. Thus, the Maxima V, Three and Four Wheel Scooters are substantially equivalent to the predicate devices, have passed all the necessary testing, and are considered to be safe for user operation.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 11 2009

Pride Mobility Products Corporation
% Mr. Thomas Schappert
Official Correspondent
182 Susquehanna Avenue
Exeter, Pennsylvania 18643

Re: K091113
Trade/Device Name: Maxima V, Three and Four Wheel Scooters
Regulation Number: 21 CFR 890.3800
Regulation Name: Motorized three-wheeled vehicle
Regulatory Class: II
Product Code: INI
Dated: April 10, 2009
Received: April 17, 2009

Dear Mr. Schappert:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please contact the CDRH/Office of Surveillance and Biometrics/Division of Postmarket Surveillance at 240-276-3464. For more information regarding the reporting of adverse events, please go to http://www.fda.gov/cdrh/mdr/.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative,
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Exhibit 3

Indications for Use

510(k) Number (if known): K

Device Name: Maxima V, Three and Four Wheel Scooters

Indications for Use:

The intended use of the Pride Mobility Products Corporation Maxima V, Three and Four Wheel Scooters, is to provide mobility to disabled persons having limited walking capabilities.

Prescription Use X **AND / OR** **Over-The-Counter Use** X
(Part 21 CFR 801 Subpart D) **(21 CFR 807 Subpart C)**

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K091113